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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,234	02/28/2005	Hirofumi Doi	3190-072	7447

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400 HOLIDAY COURT
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EXAMINER	
SWOPE, SHERIDAN	
ART UNIT	**PAPER NUMBER**
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,234	DOI ET AL.	
	Examiner	Art Unit	
	Sheridan L. Swope	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 97-145* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1 and 97-145* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1 and 97-145 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 95, 96, and 100-103, drawn to a method for degrading a transcription factor using calpain.

Group II, claim(s) 97-99, drawn to a calpain.

Group III, claim(s) 104-106, drawn to a method for degrading a transcription factor using altered calcium concentrations.

Group IV, claim(s) 107-115 and 123-128, drawn to a method for inhibiting degradation of a transcription factor using a calpain inhibitor.

Group V, claim(s) 116-122, 129, and 135-137, drawn to a calpain inhibitor.

Group VI, claim(s) 130-134, drawn to a method of treatment using a calpain inhibitor.

Group VII, claim(s) 138-142, drawn to a method for identifying a calpain inhibitor.

Group VIII, claim(s) 143-145, drawn to a kit.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons. The technical feature linking Groups I- VIII appears to be that they all relate to calpain proteases. However, calpain proteases were well known in the art. Moreover, Watt et al, 1993 (IDS) teach calpain proteases, which anticipates Claims 97 and

98. Therefore Groups I- VIII share no special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Furthermore, the products of Groups II, V, and VIII do not share a special common structural and functional feature while, the methods of Groups I, III, IV, VI, and VII do not use the same reagents or produce the same results. In addition, the methods of Groups I, III, IV, VI, and VII do not comprise all of the methods for making or using the products of Groups II, V, and VIII. Accordingly, Groups I- VIII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Election of Species

This application contains claims directed to the following patentably distinct species.

If Invention I is elected, elect one of:

Wherein the system is:

(A) In vitro

(B) In a cellular system

(C) In vivo

If Invention I is elected, also elect one of:

Wherein the calpain is:

(D) m-calpain

(E) μ-calpain

(F) A calpain other than m-calpain or μ-calpain

If Invention I is elected, also elect one of:

Wherein the transcription factor is:

(G) Hepatocyte nuclear factor 4α

(H) Hepatocyte nuclear factor 1α

(I) Insulin promoter factor 1

(J) A transcription factor other than Hepatocyte nuclear factor 4α, Hepatocyte nuclear factor 1α, or Insulin promoter factor 1

If Invention II is elected, elect one of:

Wherein the calpain is:

(K) m-calpain

(L) μ-calpain

(M) A calpain other than m-calpain or μ-calpain

If Invention II is elected, also elect one of:

Wherein the transcription factor is:

(N) Hepatocyte nuclear factor 4α

(O) Hepatocyte nuclear factor 1α

(P) Insulin promoter factor 1

(Q) A transcription factor other than Hepatocyte nuclear factor 4α, Hepatocyte nuclear factor 1α, or Insulin promoter factor 1

If Invention III is elected, elect one of:

Wherein the transcription factor is:

(R) Hepatocyte nuclear factor 4α

(S) Hepatocyte nuclear factor 1α

(T) Insulin promoter factor 1

(U) A transcription factor other than Hepatocyte nuclear factor 4α, Hepatocyte nuclear factor 1α, or Insulin promoter factor 1

If Invention IV is elected, elect one of:

Wherein the system is:

(V) In vitro

(W) In a cellular system

(X) In vivo

If Invention IV is elected, also elect one of:

Wherein the substance is:

(Y) An antibody to the transcription factor

(Z) A calpain inhibitor

If Invention (Z) is elected, elect one of:

(i.) N-Acetyl-Leu-Leu-Met-CHO

(ii.) N-Acetyl-Leu-Leu-Nle-CHO

(iii.) Z-Leu-Leu-Tyr-CH_2F

(iv.) Mu-Val-HPh-CH_2F

(v.) 4-fluorophenylsulfonyl-Val-Leu-CHO

(vi.) Leu-Leu-Phe-CH_2Cl

(vii.) Z-Val-Phe-CHO

(viii.) A specific combination of (i)-(vii)

(ix.) A compound other than (i)-(viii)

(QQ) A peptide comprising a calpain-recognized cleavage site

If Invention (AA) is elected, elect one of:

(x.) SEQ ID NO: 1

(xi.) SEQ ID NO: 2

(xii.) SEQ ID NO: 3

(xiii.) Leu-Tyr, Leu-Met

(xiv.) Leu-Arg, Val-Tyr

(xv.) Val-Met and Val-Arg

(xvi.) A peptide other than (x)-(xvi)

If Invention IV is elected, also elect one of:

Wherein the calpain is:

(BB) m-calpain

(CC) μ-calpain

(DD) A calpain other than m-calpain or μ-calpain

If Invention IV is elected, also elect one of:

Wherein the transcription factor is:

(EE) Hepatocyte nuclear factor 4α

(FF) Hepatocyte nuclear factor 1α

(GG) Insulin promoter factor 1

(HH) A transcription factor other than Hepatocyte nuclear factor 4α, Hepatocyte nuclear factor 1α, or Insulin promoter factor 1

If Invention IV is elected, also elect one of:

Wherein the glucose metabolism-related gene is:

(II) The insulin gene

(JJ)The glucose transporter 2 gene

(KK) A gene other than the insulin or glucose transporter 2 gene

If Invention V is elected, elect one of:

Wherein the agent:

(LL) Inhibits calpain activity

(MM)Inhibits calpain binding

(NN) An activity other than (LL)-(MM)

If Invention V is elected, also elect one of:

Wherein the agent:

(OO) An antibody to the transcription factor

(PP) A calpain inhibitor

If Invention (PP) is elected, elect one of:

(x.) N-Acetyl-Leu-Leu-Met-CHO

(xi.) N-Acetyl-Leu-Leu-Nle-CHO

(xii.) Z-Leu-Leu-Tyr-CH_2F

(xiii.) Mu-Val-HPh-CH_2F

(xiv.) 4-fluorophenylsulfonyl-Val-Leu-CHO

(xv.) Leu-Leu-Phe-CH_2Cl

(xvi.) Z-Val-Phe-CHO

(xvii.) A specific combination of (i)-(vii)

(xviii.) A compound other than (x)-(xvii)

(QQ) A peptide comprising a calpain-recognized cleavage site

If Invention (QQ) is elected, elect one of:

(x.) SEQ ID NO: 1

(xi.) SEQ ID NO: 2

(xii.) SEQ ID NO: 3

(xiii.) Leu-Tyr, Leu-Met

(xiv.) Leu-Arg, Val-Tyr

(xv.) Val-Met and Val-Arg

(xvi.) A peptide other than (x)-(xvi)

If Invention V is elected, also elect one of:

Wherein the agent is useful for treating a disease attributable to degradation of:

(RR) Hepatocyte nuclear factor 4α

(SS) Hepatocyte nuclear factor 1α

(TT) Insulin promoter factor 1

(UU) A transcription factor other than Hepatocyte nuclear factor 4α, Hepatocyte nuclear factor 1α, or Insulin promoter factor 1

If Invention V is elected, also elect one of:

Wherein the agent is useful for treating a disease attributable to:

(VV) A decrease in a product of the insulin gene

(WW) A decrease in a product of the glucose transporter 2 gene

(XX) A decrease in a product of the insulin and glucose transporter 2 gene

If Invention V is elected, also elect one of:

Wherein the agent is useful for treating:

(YY) Diabetes

(ZZ) Liver adenoma

(AAA) Hepatocellular carcinoma

(BBB) A disease other than (YY)-(AAA)

If Invention VI is elected, elect one of:

Wherein the method:

(CCC) Inhibits calpain activity

(DDD) Inhibits calpain binding

(EEE) Affects an activity other than (BBB)-(CCC)

If Invention VI is elected, also elect one of:

Wherein the method treats a disease attributable to degradation of:

(FFF) Hepatocyte nuclear factor 4α

(GGG) Hepatocyte nuclear factor 1α

(HHH) Insulin promoter factor 1

(III) A transcription factor other than Hepatocyte nuclear factor 4α, Hepatocyte nuclear factor 1α, or Insulin promoter factor 1

If Invention VI is elected, also elect one of:

Wherein the method is useful for treating a disease attributable to:

(JJJ) A decrease in a product of the insulin gene

(KKK) A decrease in a product of the glucose transporter 2 gene

(LLL) A decrease in a product of the insulin and glucose transporter 2 gene

If Invention VI is elected, also elect one of:

(MMM) Wherein the method:

(NNN) Inhibits calpain activity

(OOO) Inhibits calpain binding

(PPP) Has effect other than (MMM)-(OOO)

If Invention VI is elected, also elect one of:

Wherein the method is useful for treating:

(QQQ) Diabetes

(RRR) Liver adenoma

(SSS) Hepatocellular carcinoma

(TTT) A disease other than (QQQ)-(SSS)

If Invention VII is elected, elect one of:

Wherein the method detects:

(UUU) Calpain activity

(VVV) Calpain binding

(WWW) A function other than ()-()

If Invention VII is elected, also elect one of:

Wherein the method analyzes:

(XXX) m-calpain

(YYY) μ-calpain

(ZZZ) A calpain other than m-calpain or μ-calpain

If Invention VII is elected, also elect one of:

Wherein the method analyzes:

(AAAA) Hepatocyte nuclear factor 4α

(BBBB) Hepatocyte nuclear factor 1α

(CCCC) Insulin promoter factor 1

(DDDD) A transcription factor other than Hepatocyte nuclear factor 4α, Hepatocyte nuclear factor 1α, or Insulin promoter factor 1

If Invention VIII is elected, elect one of:

Wherein the kit comprises:

(EEEE) A calpain

(FFFF) A polynucleotide encoding a calpain

(GGGG) A transcription factor encoding a glucose metabolism-related gene degraded by calpain

(HHHH) A polynucleotide encoding a transcription factor encoding a glucose metabolism-related gene degraded by calpain

(IIII) A specific combination of (EEEE)-(HHHH)

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1, 97, 104, 105, 107, 116, 123, 130, 138, 143 are generic.

Restriction for examination purposes as indicated is proper because the inventions listed in this action do not have unity of invention for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention and species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR

1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions and/or species are not distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Restriction between product and process claims has been required. Where Applicant elects claims directed to a product, and the product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. 821.04, *In re* Ochiai, and *In re* Brouwer). Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right, if the amendment is presented prior to final rejection or allowance, whichever is earlier. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. To be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.
Art Unit 1652

SHERIDAN SWOPE, PH.D.
PRIMARY EXAMINER